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EXAMINER	
MORNHINWEG, JEFFREY	
ART UNIT	PAPER NUMBER
1789	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,006	DUAN ET AL.	
	Examiner	Art Unit	
	JEFFREY MORNHINWEG	1789	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1-5, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitchell et al. (U.S. 4,894,242).**

3. Regarding claim 1, Mitchell et al. discloses a process for producing a rice protein concentrate comprising:

enzymatically hydrolyzing a rice substrate with an enzyme having granular starch hydrolyzing (GSH) activity (specifically, glucoamylase) (C3, L44-L46; C3, L63-L64) and a second starch hydrolyzing enzyme (specifically, alpha-amylase) (C3, L40-L43) at a temperature at or below 72°C (specifically, 30°C to 100°C) (C6, L7-L11, L16) and at a pH of about 3.0 to 6.5 (specifically, a pH of from 3.5 to 7.5) (C6, L20-L22) for a period of time sufficient for the hydrolysis of a substantial portion of the starch in the rice substrate (specifically, two hours) (C8, L50, where the specification of the present application indicates an appropriate incubation time is from about 2 to 100 hours at p. 26, ll. 24-28) to obtain a solubilized starch fraction and a residue fraction which includes insoluble protein; and

separating the solubilized starch fraction from the residue to obtain a rice protein concentrate (C8, L51).

4. As for claim 2, Mitchell et al. discloses the enzyme having GSH activity as being a glucoamylase (C3, L44-L46; C3, L63-L43).

5. As for claim 3, Mitchell et al. discloses the glucoamylase (i.e., a glucosidase) as being derived from a strain of *Rhizopus* or *Aspergillus* (C6, L22-L26).

6. As for claim 4, Mitchell et al. discloses the second starch hydrolyzing enzyme as being an alpha-amylase (C3, L40-L43).

7. As for claim 5, Mitchell et al. discloses the alpha-amylase as being derived from a bacterial source (specifically, a strain of *Bacillus*) (C6, L11-L14).

8. As for claim 10, Mitchell et al. discloses the rice substrate as being slurried and having a dry solid content of between 10 to 55% (specifically, 25-40% dry weight rice) (C3, L40-L42).

9. As for claim 11, Mitchell et al. discloses the temperature as being between 55°C and 70°C (specifically, 30°C to 100°C) (C6, L7-L11, L16; C8, L50).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. **Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell et al. (U.S. 4,894,242) in view of Radford et al. (U.S. 5,834,191).**

13. Regarding claim 6, Mitchell et al. discloses the process according to claim 1.

14. Mitchell et al. does not disclose the enzyme having GSH activity as being obtained from the heterologous expression of a GSH enzyme in a *Trichoderma* strain or an *Aspergillus* strain.

15. However, Radford et al. discloses the use of *Aspergillus* strains for heterologous expression of hydrolytic enzymes such as glucoamylase (C1, L17-L22, L51-L54).

16. It would have been obvious to one having ordinary skill in the art to incorporate the enzyme produced in Radford et al. into the process of Mitchell et al. Radford et al. indicates glucoamylase produced by heterologous expression in *Aspergillus* is useful in industrial processes such as "the saccharification of starch" (C1, L12-L15) or "the production of glucose syrups from starch" (C1, L65-L66). Mitchell et al. discloses a process involving the saccharification of starch in rice with glucosidase to produce a rice milk (Mitchell et al., C3, L44-L46) or rice syrup (Mitchell et al., C2, L33-L47). Therefore, it would have been obvious to one having ordinary skill in the art to incorporate enzymes produced according to Radford et al. into the method disclosed in Mitchell et al.

17. **Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell et al. (U.S. 4,894,242) in view of Puski et al. (U.S. 4,830,861).**

18. Regarding claim 7, Mitchell et al. discloses the process according to claim 1.

19. Mitchell et al. does not disclose the step of purifying the rice protein concentrate.

20. However, Puski et al. discloses a step of separating rice syrup from high protein rice flour, which is effectively a purification step (C4, L18-L19).

21. It would have been obvious to one having ordinary skill in the art to incorporate the purification step disclosed in Puski et al. with the process disclosed in Mitchell et al. The process disclosed in Puski et al.—enzymatically modifying rice flour (C2, L10-L22)—is similar to that disclosed in Mitchell et al., although the two processes are primarily aimed at recovering different byproducts. The process disclosed in Puski et al. is aimed at recovering a high-protein rice flour (C3, L43-L44), while the process disclosed in Mitchell et al. is aimed at recovering a rice milk (C2, L53-L56). Since the resulting high-protein rice flour of Puski et al. has nutritional value and is useful in infant formula (Puski et al., C1, L15-L29, L36-L49; C4, L40), a skilled practitioner would recover the second by-product—the insoluble protein—from the process disclosed in Mitchell et al. in order to produce two rice products having economic value. Thus, it would have been obvious to a skilled practitioner to recover and purify the resulting insoluble protein from the process disclosed in Mitchell et al.

22. As for claim 8, Puski et al. discloses drying the rice protein concentrate (C4, L37-L39).

23. As for claim 9, Puski et al. discloses a process wherein the protein content of the rice protein concentrate is at least about 20% (specifically, 44%) (C16, L65-L67).

24. **Claims 12-16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell et al. (U.S. 4,894,242) in view of Euber et al. (U.S. 4,990,344).**

25. Regarding claim 12, Mitchell et al. discloses enzymatically hydrolyzing a rice substrate with an enzyme having GSH activity (specifically, glucoamylase) (C3, L44-L46; C3, L63-L64) and a starch hydrolyzing enzyme (specifically, alpha-amylase) (C3, L40-L43) at a pH of about

3.0 to 6.5 (specifically, a pH of from 3.5 to 7.5) (C6, L20-L22) and at a temperature range of 55°C to 70°C (specifically, 30°C to 100°C) (C6, L7-L11, L16; C8, L50) to obtain a fraction including solubilized starch and insoluble rice protein ; and separating the fractions to obtain a rice protein concentrate (C8, L51).

26. Mitchell does not disclose repeating these steps again on a rice protein concentrate in order to obtain a high-purity rice protein concentrate.

27. However, Euber et al. discloses a similar rice protein purification process (C7, L41-L57), wherein "protein levels approaching 90% to 100% can be achieved with increased water to rice ratios and wash steps" (C8, L40-L42).

28. It would have been obvious to one having ordinary skill in the art to repeat the steps disclosed in Mitchell et al. in obtaining a high-purity protein product as disclosed in Euber et al. Euber et al. indicates protein purity in rice products as high as 100% is attainable. A skilled practitioner would find obvious the repetition of the enzymatic hydrolysis to further increase a lower-purity rice protein product obtained by previous hydrolysis in order to increase the protein purity.

29. As for claim 13, Euber et al. discloses drying the high-purity rice protein concentrate (C12, L35-L36).

30. As for claim 14, Mitchell et al. discloses the starch hydrolyzing enzyme as being an alpha-amylase (C3, L40-L43).

31. As for claim 15, Euber et al. discloses protein levels approaching 90% to 100% (C8, L40-L42).

32. As for claim 16, Mitchell et al. and Euber et al. disclose rice protein concentrates obtained according to claims 1 and 12 (Mitchell et al., C8, L50-L52; Euber et al., C12, L35-L36).

33. As for claim 18, Euber et al. discloses a human food formulation comprising the rice protein concentrate obtained according to the process of claim 1 or claim 12 (C6, L29-L31).

34. **Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell et al. (U.S. 4,894,242) in view of Euber et al. (U.S. 4,990,344) as applied to claim 12 above, and further in view of Mihara et al. (U.S. 3,852,504).**

35. Regarding claim 17, Mitchell et al. and Euber et al. disclose the rice protein concentrate according to the process of claim 1 and claim 12.

36. The cited prior art does not disclose an animal feed formulation comprising the rice protein concentrate.

37. However, Mihara et al. discloses a rice protein product that is highly nutritious (C3, L10-L12), as well as a crude rice fiber product containing some protein that is "sufficiently nutritious to be used as an animal feed" (C3, L64-C4, L2).

38. It would have been obvious to one having ordinary skill in the art to incorporate the animal feed formulation disclosed in Mitchell et al. and Euber et al. into an animal feed as disclosed in Mihara et al. Mihara et al. indicates rice-bran is useful as an animal feed (C1, L12-L13). A skilled practitioner would therefore find it obvious to incorporate a high-purity rice protein product in animal feed due to it high nutritive value.

39. **Claims 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell et al. (U.S. 4,894,242) in view of Puski et al. (U.S. 4,830,861), Euber et al. (U.S. 4,990,344) and Mihara et al. (U.S. 3,852,504).**

40. Regarding claim 19, Mitchell et al. discloses a process comprising:

contacting a rice substrate with a combination of enzymes which include a starch hydrolyzing enzyme (specifically, alpha-amylase) and a granular starch hydrolyzing (GSH) enzyme (specifically, glucoamylase) (C3, L40-L46; C3, L63-L64) at a temperature below 72°C (specifically, 30°C to 100°C) (C6, L7-L11, L16);

obtaining a solubilized starch fraction and a residue, the residue including insoluble protein (C8, L50-L52, where sieving the slurry would result in a retentate including insoluble protein);

separating the residue to obtain a rice protein concentrate (C8, L51).

41. Mitchell et al. does not disclose the duration of hydrolysis to be for a sufficient period of time to hydrolyze 60% of the starch in the rice substrate; or adding the rice protein concentrate to an animal feed.

42. However, Puski et al. indicates "[t]he length of amylase treatment is determined by the degree of starch hydrolysis required to achieve acceptable HPRF [High Protein Rice Flour] protein level" (C7, L6-L9). Euber et al. discloses a similar rice protein purification process (C7, L41-L57), wherein "protein levels approaching 90% to 100% can be achieved" (C8, L40-L42). Mihara et al. discloses a rice protein product that is highly nutritious (C3, L10-L12), as well as a crude rice fiber product containing some protein that is "sufficiently nutritious to be used as an animal feed" (C3, L64-C4, L2).

43. It would have been obvious to one having ordinary skill in the art to combine the process disclosed in Mitchell et al. with the additional conditions disclosed in Puski et al. and Euber et al. and the use of the product as disclosed in Mihara et al. Puski et al. indicates removal of carbohydrates from rice has the effect of concentrating the protein in order to create a rice product having a higher nutritional value (C1, L40-L44). Euber et al. provides higher protein concentrations than those considered in Puski et al. and would be consulted by a skilled practitioner desiring a high-purity protein rice flour. Mihara et al. indicates rice-bran is useful as an animal feed (C1, L12-L13). A skilled practitioner would therefore find it obvious to incorporate a rice protein product in animal feed due to it high nutritive value.

44. As for claim 20, Mitchell et al. discloses the starch hydrolyzing enzyme as being an alpha-amylase (C3, L40-L43).

45. As for claim 21, Mitchell et al. discloses a contacting a rice substrate with a GSH enzyme (specifically, glucoamylase) and a starch hydrolyzing enzyme (specifically, alpha-amylase) (C3, L40-L46; C3, L63-L64) enzyme to obtain a fraction including a solubilized starch and a residue comprising insoluble rice protein (C8, L50-L52, where sieving the slurry would result in a retentate including insoluble protein); and separating the residue to obtain a rice protein concentrate (C8, L51).

46. Mitchell does not disclose repeating these steps again on a rice protein concentrate in order to obtain a high-purity rice protein concentrate, or adding the high-purity rice protein concentrate to an animal feed.

47. However, Euber et al. discloses a similar rice protein purification process (C7, L41-L57), wherein "protein levels approaching 90% to 100% can be achieved with increased water to rice

ratios and wash steps" (C8, L40-L42). Mihara et al. discloses a rice protein product that is highly nutritious (C3, L10-L12), as well as a crude rice fiber product containing some protein that is "sufficiently nutritious to be used as an animal feed" (C3, L64-C4, L2).

48. It would have been obvious to one having ordinary skill in the art to repeat the steps disclosed in Mitchell et al. in obtaining a high-purity protein product as disclosed in Euber et al. Euber et al. indicates protein purity in rice products as high as 100% is attainable. A skilled practitioner would find obvious the repetition of the enzymatic hydrolysis to further increase a lower-purity rice protein product obtained by previous hydrolysis in order to increase the protein purity. Also, Mihara et al. indicates rice-bran is useful as an animal feed (C1, L12-L13). A skilled practitioner would therefore find it obvious to incorporate a rice protein product in animal feed due to it high nutritive value.

49. As for claim 22, Mihara et al. effectively discloses an animal feed comprising the high-purity rice protein concentrate obtained according to claim 21. It would have been obvious to one having ordinary skill in the art to incorporate the animal feed formulation disclosed in Mitchell et al. and Euber et al. into an animal feed as disclosed in Mihara et al. Mihara et al. indicates rice-bran is useful as an animal feed (C1, L12-L13). A skilled practitioner would therefore find it obvious to incorporate a high-purity rice protein product in animal feed due to it high nutritive value.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY MORNHINWEG whose telephone number is (571)

270-5272. The examiner can normally be reached on Monday-Friday, 8:00AM-5:30PM, EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Humera Sheikh can be reached on (571) 272-0604. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Humera N. Sheikh/
Supervisory Patent Examiner, Art Unit 1789

/J. M./
Examiner, Art Unit 1789